

**Premarket Approval (PMA) Package for  
Dockets Management Branch**

**PMA Number P970043/S015  
Docket # 2004M-0312**

**Alcon Laboratories, Inc.  
LADARVision® 4000 Excimer Laser System**

**Includes:**

**Approval Order  
Summary of Safety and Effectiveness Data (SSED)  
Labeling**